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16 *Attorneys for Plaintiffs/Counterdefendants*  
17 *Bayer Schering Pharma AG and Bayer*  
*HealthCare Pharmaceuticals Inc.*

19 **UNITED STATES DISTRICT COURT**  
20 **DISTRICT OF NEVADA**

21 Bayer Schering Pharma AG &  
Bayer HealthCare Pharmaceuticals Inc.,

No. 2:11-cv-00604-KJD-CWH

22 Plaintiffs/Counterdefendants,

**ORDER STAYING ACTION  
PENDING APPEALS**

23 v.

24 Mylan Pharmaceuticals Inc., Mylan Inc.,  
and Famy Care Ltd.,

26 Defendants/Counterclaimants.

1           WHEREAS, Bayer is the owner of, among others, U.S. Reissue Patent No. 37,564; (the  
2 “Patent-In-Suit”), and is the holder of an FDA-approved New Drug Application No. 21-676 for  
3 YAZ® brand tablets for the prevention of pregnancy in women who elect to use an oral  
4 contraceptive and the treatment of acne and premenstrual dysphoric disorder;

5           WHEREAS, on November 5, 2007, Bayer filed Civil Action No. 2:07-cv-01472 in this  
6 Court against Watson Pharmaceuticals, Inc. and Watson Laboratories, Inc. (“Watson”) alleging  
7 infringement of, among others, the Patent-In-Suit, based on Watson’s submission to the FDA of an  
8 Abbreviated New Drug Application (“ANDA”) seeking permission for the commercial  
9 manufacture, use, offer for sale, sale and/or importation of a generic version of Bayer’s YAZ®  
10 tablets;

11          WHEREAS, on August 1, 2008, Bayer filed Civil Action No. 2:08-cv-00995 in this Court  
12 against Sandoz, Inc. (“Sandoz”) alleging infringement of, among others, the Patent-In-Suit, based  
13 on Sandoz’s submission to the FDA of an ANDA seeking permission for the commercial  
14 manufacture, use, offer for sale, sale and/or importation of a generic version of Bayer’s YAZ®  
15 tablets;

16          WHEREAS, on November 4, 2008, United States District Judge Roger L. Hunt entered an  
17 order granting Bayer’s motion to consolidate the foregoing actions under Civil Action No. 2:07-  
18 01472 (hereinafter the “Watson/Sandoz Action”);

19          WHEREAS, on July 15, 2010, Bayer filed Civil Action No. 2:10-cv-01166 in this Court  
20 against Lupin Ltd. and Lupin Pharmaceuticals, Inc. (“Lupin”) alleging infringement of, among  
21 others, the Patent-In-Suit based upon Lupin’s submission to the FDA of an ANDA seeking  
22 permission for the commercial manufacture, use, offer for sale, sale and/or importation of a  
23 generic version of Bayer’s YAZ® tablets (hereinafter the “Lupin Action”);

24          WHEREAS, on April 19, 2011, Bayer filed this action (the “Mylan Action”) against  
25 Mylan Pharmaceuticals, Inc., Mylan Inc., and Famy Care Ltd. alleging infringement of the Patent-  
26 In-Suit based upon the submission to the FDA of an ANDA seeking permission for the  
27 commercial manufacture, use, offer for sale, sale and/or importation of a generic version of  
28 Bayer’s YAZ® tablets (“the ANDA Product”);

1           WHEREAS, this action involves the same patent-in-suit as the Watson/Sandoz Action and  
2 the Lupin Action;

3           WHEREAS, in the Watson/Sandoz Action, on March 30, 2012, this Court granted Bayer's  
4 motion for summary judgment finding that the Patent-In-Suit was both valid and enforceable  
5 against Watson and Sandoz (No. 07-1472, Dkt. No. 333);

6           WHEREAS, the Court entered Watson and Sandoz's motion for partial final judgment on  
7 May 29, 2012 (No. 07-1472, Dkt. No. 354);

8           WHEREAS, in the Lupin Action, on March 30, 2012, the Court granted Bayer's motion  
9 for summary judgment finding that the Patent-In-Suit was both valid and enforceable against  
10 Lupin (No. 10-1166, Dkt. No. 106);

11          WHEREAS, Watson, Sandoz, and Lupin have appealed the Court's judgment that the  
12 Patent-In-Suit is not invalid as obvious to the United States Court of Appeals for the Federal  
13 Circuit (No. 07-1472, Dkt. Nos. 341-342, 355-356; No. 10-1166, Dkt. No. 112);

14          WHEREAS, these appeals (all concerning the same patent and the same issues) are  
15 currently pending before the United States Court of Appeals for the Federal Circuit in Case Nos.  
16 2012-1397, 2012-1398, 2012-1400, and 2012-1424 (the "Pending Appeals"); and

17          WHEREAS, Plaintiffs Bayer Schering Pharma AG and Bayer HealthCare  
18 Pharmaceuticals, Inc. (collectively "Bayer"), on the one hand, and Defendants Mylan  
19 Pharmaceuticals, Inc., Mylan Inc., and Famy Care Ltd. (collectively "Defendants"), on the other  
20 hand, have jointly moved the Court to stay this action pending the Federal Circuit's resolution of  
21 Watson's, Sandoz's, and Lupin's appeals to the Federal Circuit of judgments issued by the Court  
22 holding that the patent at issue in this case is valid and enforceable and not obvious;

23          It is **HEREBY ORDERED:**

24          1.       This action is stayed in its entirety pending resolution of the Pending Appeals by  
25 the Federal Circuit, including any subsequent appeals of the Federal Circuit's decision to the  
26 United States Supreme Court. The stay of this action shall have no effect on any statutory stay of  
27 FDA approval of ANDA No. 20-2594 imposed under the Hatch Waxman Act, 21 U.S.C. §  
28 355(j)(5)(B)(iii).

1           2. All of Defendants' counterclaims are hereby stayed in their entirety pending  
2 resolution of the pending appeals by the Federal Circuit, including any subsequent appeals of the  
3 Federal Circuit's decision to the United States Supreme Court.

4       3. Notwithstanding the foregoing, Bayer or Defendants may move to lift the stay of  
5 this action for good cause shown, which includes: (a) settlement or any other type of stipulated,  
6 consent or otherwise agreed final judgment with or without a ruling on the merits as to any  
7 defendant in the pending appeals; (b) an actual or threatened launch by Defendants of the ANDA  
8 Product; and (c) any other circumstance which, in the District Court's judgment, renders  
9 enforcement of this stipulation unjust or inequitable.

10       4. Should the stay of this action be lifted, the parties shall complete discovery and  
11 amend the remaining case schedule to avoid further delay such that this action will not be  
12 otherwise affected by this stay, to the extent practicable.

13           5.      Bayer and Defendants shall confer regarding any issues remaining in the case after  
14 the resolution of the Pending Appeals.

## **IT IS SO ORDERED:**



DATED: October 5, 2012